Brief Communication

Compliance with International Committee of Medical Journal Editors policy on individual participant data sharing in clinical trial registries: An audit

INTRODUCTION

The popularity of open data movement and methodological developments in the conduct of individual participant data (IPD) meta-analysis and secondary analysis has led to increased calls for sharing of IPD of clinical trials.[1] Sharing of adequately deidentified IPD also enhances reproducibility, data quality, and utility. The International Committee of Medical Journal Editors (ICMJE) made it mandatory[2] for all trials, which began enrolling participants from January 1, 2019, to have an IPD data sharing plan. The policy requires the data sharing plan to provide adequate information through answers to a broad question and six subfields. Subsequently, the World Health Organization had added IPD sharing-related fields in the mandatory data field required in its International Clinical Trials Registry Platform (ICTRP) which trialists provide.[3] In this study, we aimed to examine how information on trialists' intent for IPD sharing is captured in different clinical registries globally and if they complied with the ICMJE policy.

METHODS

We audited 18 clinical trial registries (February 21–25, 2022) which were listed as primary registry or data providers in the WHO ICTRP network [Supplementary Data 1 available Online at https://doi.org/10.6084/m9.figshare.20487870.v1]. We extracted data from fields and subfields related to IPD sharing from each of the registries from their publicly available data dictionaries (if available), checked trial registration fields in a mock account, or reviewed at least 10 most recent trial records of that registry for its IPD-related fields. Two auditors independently made decisions (yes or no) on the concurrence of the IPD data requirement of each registry with the IPD data policy of the ICMJE. We resolved disagreement (two such) in a consensus meeting.

RESULTS

We found that 17 (94.44%) of the 18 registries had a specific field requiring information on sharing of IPD. The European Union Clinical Trials Registry had no field to collect information on IPD statements. There is considerable heterogeneity in the manner of how trialists are required to record IPD data sharing intent in these 17 registries [Supplementary Data 2 available Online at https://doi.org/10.6084/m9.figshare.20487870.v1]. The data captured in relation to IPD sharing complied with the ICMJE policy in only 4 (22.22%) registries – Australian New Zealand Clinical Trials Registry (ANZCTR), Clinical Trials Registry of India (CTRI), Iranian Registry of Clinical Trials (IRCT), and the US trial registry (ClinicalTrials.gov). Trial registries often did not capture one or more of the required data parameters of the ICMJE policy or had a free text option without structuring to capture all requisite data.

DISCUSSION

There has been progress with respect to IPD sharing information availability in trial registries, with all excepting one (Europe) having an IPD field. However, there is little consistency, with only four trial registries capturing data in a structured manner on all relevant parameters in concurrence with ICMJE policy. Audits of data sharing statements of published clinical trials indicate considerable confusion and uncertainty among trialists about what IPD data sharing entails.[4] The practical implication of this is the requirement of those seeking IPD for meta-analysis, secondary analysis, or reanalysis needing substantial resource and time investment to clarify trialist intent and process for sharing IPD data.[5] Clinical trial registries can play a key role in enabling this process. Structuring IPD data fields and their subfields in alignment with ICMJE standards with minimal use of free texts, as done by ANZCTR, CTRI, IRCT, and US trial registry, would ensure consistency. Clinical trial registries should additionally make their updated data dictionaries public and enable downloading of all IPD-related fields and subfields from their website to improve user functionality, enhance transparency, and enable an analysis of trial registry records.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Access this article online	
Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.picr_85_22

How to cite this article: Borana R, Bhaumik S. Compliance with International Committee of Medical Journal Editors policy on individual participant data sharing in clinical trial registries: An audit. Perspect Clin Res 2022;13:213-4.

Received: 06-04-22, **Accepted:** 15-04-22, **Published:** 12-09-22.